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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,208	08/24/2001	Gregory E. Agoston	05213-0852 (43170-263550)	3573

7590 11/18/2002

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,208

Applicant(s)

AGOSTON ET AL.

Examiner

Sabiha Naim Qazi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-92 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-92 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Inventions of group I –VI and IX-X are different from each other due to various substituents at different positions of cyclopentanophenanthrene ring. Each will require separate search.

There is no significant common structural element on which the utility is described. As is clear from the structures that the invention is different from each other and one reference applied to reject the invention of one group cannot be used for any other group for the same reason. Separate searches are required for each of the groups. They are patent ably distinct. For example Ra represents NHC (O) R6, -NRC (O) R6, NH2, or N (R6)(R7), O-R, O-R-R1, OR (O) R, OR (O) R1, R-R1, ROR, ROR1, N3, -C=N, CH2-C=N, C=CH-R, R-CH=CH2, >C (H)-C (O)-OR3, CH2-C=R, -C=C-R, -C=CH; similarly each substituent can have list of substituents which constitute multitude of compounds. It would be a burden on the Examiner to search all the invention in this application.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for any other Group, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Attorney Suzanne Seavello Shope on 11/15/02 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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El ction/Restrictions

Claims 1-92 are pending.

This application is a CIP of US 09/933,894, filed August 21, 2001, which is a C IP of 09/641,327, filed August 18, 2000; this application also claims the benefit of US Provisional Application 60/253,385, filed Nov. 27, 2000; US 60/278,250, filed March 23, 2001. The response filed in paper no. 11 after the telephonic interview with Attorney Susanne Shope and Attorney David E. Wigley is acknowledged. Examiner is thankful for both Mr. Wigley and Ms. Scope for their cooperation regarding the issue of double Patenting raised by the Examiner. The applications 09/641,327, 09/939,208, 09/779,331 and 09/899,702 are commonly owned. New restriction requirement is made in view of complexity and multitude of compounds and their method of use, which is instantly claimed. In addition to substituents, B, C and D rings can be unsaturated at any position, all these constitute thousands of compounds, which would be restricted. The restriction mailed in paper no. 4 is withdrawn and new restriction requirement is as follows.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is N_3 , $-C=N$, $CH_2-C=N$; Z' is $>CH-OH$; Z'' is $>CH_2$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- II, Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $R-R_1$, ROR , ROR_1 ; R_b is H; R_g is $>CH-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- III. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $NHC(O)R_6$, $-NRC(O)R_6$, NH_2 , or $N(R_6)(R_7)$; R_b is H; R_g is $>C-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- IV. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $O-R$, $O-R-R_1$, $OR(O)R$, $OR(O)R_1$; R_b is H; R_g is $>CH-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).

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- V. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $CH_2-C=R$, $-C=C-R$, $-C=CH$; R_b is H; R_g is $>CH-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- VI. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $-C=CH-R$, $R-CH=CH_2$, $>C(H)-C(O)-OR_3$; R_b is H; R_g is $>C-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- VII. Claim 16 is drawn to a method of modifying estradiol analogs for preventing or hindering demethylation, oxidation and conjugation with another molecule during metabolism, class 552, subclass 169, 171, 182.
- VIII. Claim 17 is drawn to the method of modifying estradiol analogs which comprises adding steric bulk or modification of chemical or electrostatic characteristics or a combination thereof to estradiol analogs for retarding or preventing metabolic deactivation, class 552, subclass 169, 172, 182.
- IX. Claims 1-15 and 18-92 drawn to the compounds when R_0 is H; Z' is $>C-OH$; Z'' is $>CH_2$; R_a is $-C=CH-R$, $R-CH=CH_2$, $>C(H)-C(O)-OR_3$; R_b is as defined; R_g is $>C-OH$ or $=CH_2$; R_{h1} and R_{h2} is H; and B, C and D rings are saturated, classified in class 552, subclass (various).
- X. Claims 1-15 and 18-92 drawn to compounds not covered by any other groups cited above.

The inventions are distinct, each from the other because of the following reasons:

Inventions of group I-VI and VII-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using the product.

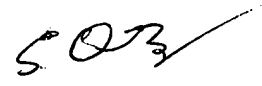
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

November 18, 2002



SABIHA QAZI, PH.D
PRIMARY EXAMINER